

PV-0087

Non-publication of Phase-3 clinical trials in radiotherapy

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Purpose or Objective: As of 1 July 2015 The ClinicalTrials.gov database was searched for interventional phase-3 trials in radiotherapy with a primary completion date before 1 January 2013. According to the 2007 Act of the FDAAA results of applicable clinical trials are due not later than 12 months after the primary completion date. Our objective was to determine how many of these trials have not been published a deposition of their results within the register yet.

Material and Methods: A first study sample consisted of 802 interventional phase-3 clinical trials with a primary completion date before 1 January 2013. We also took a sample which was a subset of the former one, taking into account only the interventional phase-3 clinical trials with a study start as of 1 January 2008; the main reason was to see if those trials starting after the 2007 Act publish more results within the register as the trials registered before the 2007 Act was passed.

Results: In our first study sample, a total of 655 trials (81.7%) did not deposit a summary result. Clinical Trials starting after the 2007 Act was passed did not do any better: 422 out of 552 (76.4%) haven't published a deposition of their results within the register. We further analyzed our search results taking into account the cancer subtype. The percentages of unpublished results for our second study sample were the following: Gastric (68%), Rectal (64%), Bladder (90%), Sarcoma (70%), Linfoma (78%), Esophagus (92%), Cervix (80.6%), Astrocitoma (70%), Testicular (100%), Skin (89.5%), Eye (47%), Anal (100%), Palliative (75%), Glioblastoma (62.5%), Breast (78%), Lung (73.7%), Head&Neck (74.6%), Prostate (68. %).

Conclusion: Our results show that most trials do not report results, even if they are forced to do so after the 2007 Act. This means that a large number of study participants were exposed to the risks of trial participation without the supposed benefits that sharing and publishing results would have for future generations of patients.

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Rapid changes in brain metastasis during radiosurgical planning - implications for MRI timing

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Purpose or Objective: The aim of this prospective study was to determine any changes in brain metastases or resection cavity volumes between the planning MRI and radiosurgical (RS) treatment and if these impacted on management or led to an alteration of the RS plan.

Material and Methods: 33 patients with 42 metastases and 12 tumour resection cavities underwent a planning MRI (MRI-1) which was fused to the planning CT. GTV (metastasis) or CTV (cavity) were contoured from the T1 and T2 post-gadolinium MRI. The GTV/CTV had a 2mm circumferential expansion creating a PTV with a plan generated. In addition, a verification MRI (MRI-2) was performed 24-48 hours prior to RS with volumes re-contoured on MRI-2 (verGTV/verPTV). The GTV/CTV and PTV volume changes between MRI-1 and MRI-2 were recorded and the original plan assessed for coverage of the verPTV. A change in plan or management based on MRI-2 was recorded.

Results: Patient and tumour characteristics are shown in Table 1. The median time between MRI-1 and MRI-2 was 7 days with 27 patients (82%) having 14 days or less and 22 patients (66%) with 7 days or less. Changes in GTV/CTV and PTV volumes between MRI-1 and MRI-2 are shown in Figure 1.

19 (58%) patients required a change in management based on changes in lesions on MRI-2 including: re-planning of RS, or a change in treatment to whole-brain radiotherapy (WBRT), surgery or best supportive care (BSC). Per lesion, 30 out of 54 lesions (56%) required re-planning based on MRI-2 including 5 (42%) cavities and 25 (60%) metastases. 2 patients had rapid progression with lepto-meningeal disease diagnosed on MRI-2 and received WBRT. 1 patient (previously received WBRT) had a rapid increase in lesion size and number, with an additional 9 lesions noted on MRI-2 and received BSC. Reasons for re-planning included: increase in volume (27 lesions) with 25 verGTV lying outside the original PTV and 2 touching the original PTV; 2 lesions with a reduction in verGTV/verPTV volumes, and 3 patients with an increase in the number of metastases or leptomeningeal disease on MRI-2.

Conclusion: This study is the first to demonstrate changes in brain metastases volume from planning MRI to RS treatment, where changes often occurred with an interval of 7 days or less. An MRI performed within 24-48 hours of RS led to re-planning or a change in management in more than 50% of patients. Therefore, even a short interval between planning MRI and RS may result in a geographical miss or over treatment, emphasising the need for efficient planning processes.

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CyberKnife for prostate cancer patients - early results of 350 patients irradiation

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Purpose or Objective: The aim of this study was an evaluation of a toxicity and an early effectiveness of prostate cancer patients CyberKnife based radioablation.

Material and Methods: 350 PC patients (186 Low Risk, 164 Intermediate Risk) aged from 53 to 83 (mean 69) irradiated with CK every other day (fd 7.25Gy, TD 36.25Gy, OTT 9 days). Before the treatment start PSA varied from 0.3 to 19.5 (median 7.5) and T stage from T1c to T2c. Mean prostate dimensions were 42.6x37.2x41.1mm. FU ranged to 48 months (mean 12). Directly after the treatment, 1, 4, 8 months later and the next every 6 months, the percentage of patients with Androgen Deprivation Therapy (ADT), GI (gastro-intestinal) and GU (genito-urinary) toxicity (acute up to the 4th month and the next late) using the EORTC/RTOG scale and PSA concentration were checked.

Results: The percentage of patients without ADT increased from 42.6% to 100% 32 months later. The maximal percentage of acute G3 adverse effects was 0.5% for GI, 0.6% for GU and G2 - 1.9% for GI and 6.0% for GU. No G3 late toxicity was observed. The maximal percentage of late G2 toxicity was 0.5% for GI and 3.0% for GU. PSA median decreased from 2.2 to 0.2 ng/ml during FU. One patient relapsed (18 months after RT- next treated with salvage BT) and one developed metastasis in lymphatic node (treated next with salvage CK). The detailed results are presented in the Table.